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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,758	03/06/2008	Guy Servant	67824.431530	3144

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EXAMINER	
GUCKER, STEPHEN	
ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,758	SERVANT ET AL.	
	Examiner	Art Unit	
	STEPHEN GUCKER	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-110* is/are pending in the application.

4a) Of the above claim(s) *6,16-17 and 27-110* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-15 and 18-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-26, and SEQ ID NO:7 in the reply filed on 1/12/11 is acknowledged. Additionally, an election of species of sodium ion was made. Claims 6, 16-17, and 27-110 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/12/11.

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months

from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

3. The earliest effective filing date of the instant application is 7/10/03, the filing date of 60/485,745.

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claims 1 and 5 recite monitoring anion mediated changes in fluorescence, and in claim 5, in which an anion is sodium [sic]. Support for these claims does not appear in the specification as filed.

5. The disclosure is objected to because of the following informalities: the specification on pages 87-88 teaches that the human amiloride sensitive sodium channel delta subunit complete coding sequence has 1917 nucleotides (SEQ ID NO:7). However, both the paper copy and CRF of the sequence listing teach that the same sequence (SEQ ID NO:7) has only 1916 nucleotides. Because of this discrepancy, the sequence search of the USPTO reveals that instant SEQ ID NO:7 is only 95.4% identical to the encoding sequence of back translated amino acid sequence SEQ ID NO:8, which SEQ ID NO:7 is intended to encode. Furthermore, SEQ ID NO:8 is described as a 638 nucleotide sequence on page 88, when it actually is an amino acid sequence.

Appropriate correction is required.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5, 7-15, and 18-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-5, 7-15, and 18-26 recite methods using the genus of epithelial sodium channels (ENaC) comprising the four genuses of alpha, beta, gamma, and delta subunits, plus any variant, fragment, functional equivalent, or generic clone from human kidney, lung, or taste cell cDNA. However, the disclosure adequately teaches only one species of ENaC (human), from one type of tissue (kidney), and only one species of sequence for each of the four subunits, cloned from human kidney cDNA (see Example 1), and not human taste cell cDNA. Pages 39-40 of the specification describe methods for isolating ENaC subunit nucleic acid and orthologs, alleles, mutants, polymorphic variants, and conservatively modified variants of such, but the claims are not drawn to methods of isolating other members of the genus, or from different types of tissue, but to methods using the four genuses of subunits for a mammalian cell-based high throughput assay for the profiling and screening of putative modulators of the genus of ENaC. Therefore, the instant disclosure fails to adequately describe a representative number of all the genuses so that a common core structure belonging to each of the genuses can be ascertained by those of skill in the art to demonstrate that Applicants had possession of each of the genuses. Finally, the disclosure is silent as to the chemical or structural description of any genus that can be described as a functional equivalent of the alpha, beta, gamma, or delta subunit genuses without incorporating any limitation regarding structure, but merely described as being a “functional equivalent”.

Finally, the specification does not adequately describe monitoring anion mediated changes in fluorescence or an assay where sodium is an anion.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-5, 7-15, and 18-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because SEQ ID NO:7 is disclosed as having both 1916 and 1917 encoding nucleotides, which results in the encoded delta subunit as either having an isoleucine residue at position 584 (1917 nucleotides), or having the reading frame altered at this position. Additionally, “monitoring anion mediated changes in fluorescence" is vague and indefinite because the claims lack active process steps by which said anion mediated changes in fluorescence are produced, such as the addition of anions to the inside of the cell, the outside of the cell, or are the anion mediated changes produced by chemically stimulating the cell in some manner, electrically stimulating the cell, etc.? Alternately, do the anion mediated changes simply appear over some undefined time period or process of “monitoring”? How are the anion mediated changes to be used by the artisan to determine the extent of ENaC modulation? Does increased fluorescence mediated by anions indicate increased modulation of ENaC? Less? How do anions mediate changes in fluorescence for a sodium fluorescent dye? The instant specification is silent as to these issues of indefiniteness. Finally, sodium is a cation, not an anion (see claim 5).

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-5, 7-15, and 18-26 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 02/087306. See claims 1-12, 15-23, and 87-88 of WO 02/087306.

12. Claims 1-5, 7-15, and 18-26 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 02/087306. See claims 1-12, 15-23, and 87-88 of WO 02/087306.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

13. Claims 1-5, 7-15, and 18-26 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2004/0072254. See claims 1-12, 15-23, and 87-88 of US 2004/0072254.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: allowed application 10/887,233 (US Patent Publication 20050059094), US Patent Publication 2002/0128203, and US Patent 5,693,756.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is 571-272-0883. The examiner can normally be reached on Mondays through Fridays from 0930 to 1800.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. G./

Examiner, Art Unit 1649
Stephen Gucker
March 29, 2011

/Jeffrey Stucker/
Supervisory Patent Examiner, Art Unit 1649